UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,200	03/30/2007	Jurgen Dorn	568-PDD-03-14-US-[43P]	2020
69683 C. R. Bard, Inc.	7590 09/01/201	EXAMINER		
Bard Peripheral	Vascular, Inc.	MENDOZA, MICHAEL G		
1415 W. 3rd St PO Box 1740		ART UNIT	PAPER NUMBER	
Tempe, AZ 852	280-1740	3734		
			NOTIFICATION DATE	DELIVERY MODE
			09/01/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

BPVIP.Docket@crbard.com Jacki.Daspit@crbard.com

Office Action Summary		А	pplication No.	Applicant(s)				
		1	0/580,200	DORN, JURGEN				
		E	xaminer	Art Unit				
		М	ICHAEL G. MENDOZA	3734				
Period fo	The MAILING DATE of this communi r Reply	cation appear	s on the cover sheet with the o	correspondence ac	idress			
WHIC - Exter after - If NO - Failu Any r	CORTENED STATUTORY PERIOD FOR HEVER IS LONGER, FROM THE MASSIAN SOLUTION OF THE MASSIAN OF THE M	AILING DATE of 37 CFR 1.136(a unication. tutory period will a will, by statute, cau	E OF THIS COMMUNICATION In no event, however, may a reply be tile pply and will expire SIX (6) MONTHS from se the application to become ABANDONE	N. mely filed the mailing date of this c ED (35 U.S.C. § 133).				
Status								
1) 又	Responsive to communication(s) filed	d on <i>01 June</i>	2010					
	This action is FINAL . 2b) ☐ This action is non-final.							
′=	Since this application is in condition f	<i>′</i> —		osecution as to the	e merits is			
٠,ـــ	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Dispositi	on of Claims							
4)⊠	Claim(s) <u>1-19,21 and 22</u> is/are pendi	ng in the app	lication.					
· —	4a) Of the above claim(s) is/are withdrawn from consideration.							
	5) Claim(s) is/are allowed.							
·	Claim(s) <u>1-19, 21 and 22</u> is/are rejec	ted.						
· ·	Claim(s) is/are objected to.							
•	Claim(s) are subject to restrict	tion and/or el	ection requirement.					
	on Papers							
	The specification is objected to by the	Evaminor						
-			ad or b) abjected to by the	Evaminor				
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
					ER 1 121/d)			
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
•—	ınder 35 U.S.C. § 119	<u></u>						
	<u>-</u>	or foreign pri	ority under 25 LLC C S 110/o) (d) or (f)				
· .	12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a)	a) ☑ All b) ☐ Some * c) ☐ None of:							
	1. Certified copies of the priority documents have been received.							
	2. ☐ Certified copies of the priority documents have been received in Application No3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage							
	application from the International Bureau (PCT Rule 17.2(a)).							
* See the attached detailed Office action for a list of the certified copies not received.								
Attachmen	t(s)							
_	e of References Cited (PTO-892)		4) Interview Summary	(PTO-413)				
2) Notic	e of Draftsperson's Patent Drawing Review (P	TO-948)	Paper No(s)/Mail D	ate				
3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 6/18/2010. 5) Notice of Informal Patent Application 6) Other:								

Application/Control Number: 10/580,200 Page 2

Art Unit: 3734

DETAILED ACTION

Response to Arguments

- 1. Applicant's arguments filed 6/1/2010 have been fully considered but they are not persuasive.
- 2. The applicant argues that St. Germain does not teach a proximal guidewire exit port. The examiner disagrees. St. Germain teaches an opening, such as the openings 130 and the opening as shown in fig. 8. The broadest definition of a port is an opening. St. Germain teaches openings. Furthermore, the claim does not state that there is a guidewire within the port (however, fig. 8 does illustrate). Therefore, the openings/ports of St. Germain read on the limitation of "a proximal guidewire exit port that is distal of the proximal end.
- 3. The applicant argues that it would not have been obvious to include an outer pull ring and that the outer pull ring is not a mere duplication of parts. The examiner disagrees. The function of the pull ring is to pull the sheath to release the stent. Having a pull ring outside performs the same function and therefore is a duplicate of the inner pull ring.
- 4. The applicant argues Fig. 8 does not show a pusher tube. However, Fig. 6 show a pusher to integral with a guide tube. As previously stated, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the pusher tube and the pusher guide tube separate since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

Application/Control Number: 10/580,200 Page 3

Art Unit: 3734

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 6. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 7. Claim 19 recites the limitation "the sheath" in line 6. There is insufficient antecedent basis for this limitation in the claim.
- 8. Claim 19 recites the limitation "the pull wire" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35
U.S.C. 102 that form the basis for the rejections under this section made in this
Office action:

A person shall be entitled to a patent unless -

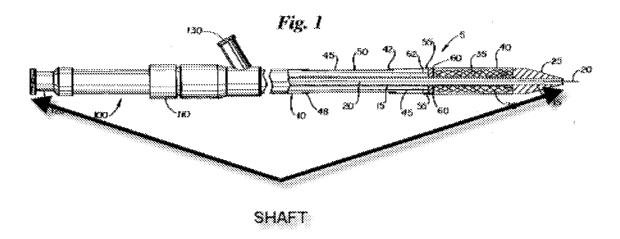
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 10. Claims 1-3, 5-8, 10-15, 19, 21, and 22 are rejected under 35U.S.C. 102(b) as being anticipated by St. Germain et al. 5534007 (St. Germain).
- 11. St. Germain teaches a catheter device comprising: a shaft (5), a medical implant (35), a guidewire (20), a flushing lumen, a proximal guidewire exit port (see fig. 8); a sheath (40) that lies radially outside the medical implant in the catheter that is proximally withdrawn form the medical implant, a first shaft

Art Unit: 3734

element including at least one of a pull wire (45) and a rod to pull the sheath proximally; and a second shaft element including a pusher tube (15), wherein the sheath comprises a tapered distal tip (25), wherein the pull wire (45) is coupled to the sheath by an inner pull ring (55) located radially inside the sheath (40), the pull wire and pull ring being both of metal and with a metal bond between the pull wire and the pull ring (col. 4, lines 24-33), wherein the sheath is polymeric and carries within its wall thickness a braid of metallic filaments (col. 3, lines 39-42), wherein the pusher tube comprises a distal end to which is fix side-by-side, the proximal end of a pusher-quider tube the defines a lumen for the guidewire (see figs. 6-8); wherein the pusher-guider tube comprises a spiral metal filament (col. 3, lines 8-17) that carries a stopper ring (60), wherein the second shaft element include the pusher tube, the pusher-guider tube and the stopper ring (see figs. 6-8), a flushing sleeve (50) that is contiguous with the sheath and defines a lumen that contains the pusher tube (see figs.), a guider block (100) that has a cylindrical outside surface to receive the flushing sleeve, a guidewire lumen, and a lumen side-by-side with the guidewire lumen to receive the pusher tube (figs. 1-5), the flushing sleeve distal of the guider-block includes a bellows tube (see compression of 50 in figs. 1-3), wherein the flushing sleeve distal of the guider block includes a telescopic tube (see compression of 50 in figs. 1-3), wherein the quide block is fixed against axial movement, wherein the proximal quidewire exit port (120 can also be used as a quidewire exit port) is immediately proximal of the guider block, wherein the medical implant devices comprises one of a selfexpanding stent (35), a stent, a stent graph, and a filter.

Art Unit: 3734

12. As to the structural limitations set forth in claims 19 and 21, it has been held that to be entitled to weight in method claims, the recited strucuture limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961).



Claim Rejections - 35 USC § 103

- 13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 14. Claims 4, 9, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over St. Germain et al.
- 15. As to claim 4, St. Germain teaches the claimed invention except for an outer puller ring. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use more than one puller ring, since it

Art Unit: 3734

has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

- 16. As to claim 9, St. Germain teaches the claimed invention except for wherein the pusher tube and the pusher guide tube are separate and held side-by-side by an adaptor block. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the pusher tube and pusher guide tube separate, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179. And furthermore, parts 140, 60, or 25 are capable of acting as an adaptor block.
- 17. As to claims 16, St. Germain teaches the claimed invention except for the claimed length of around 75 cm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed length, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.
- 18. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over St. Germain et al. in view of Sullivan et al. 6514196.
- 19. St. Germain teaches the catheter as claimed in claim 15. It should be noted that St. Germain fails to teach a steering tube.
- 20. Sullivan teaches a catheter that is combined with a common steering tube (col. 5, lines 5-17). Therefore, it would have been obvious to one having ordinary

Application/Control Number: 10/580,200

Art Unit: 3734

skill in the art to modify the catheter of St. Germain in view of Sullivan to help steer, push, or twist the device to a desired location.

Conclusion

21. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL G. MENDOZA whose telephone number is (571)272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/580,200 Page 8

Art Unit: 3734

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. G. M./ Examiner, Art Unit 3734

/TODD E. MANAHAN/ Supervisory Patent Examiner, Art Unit 3734